UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES, AND
TOXIC SUBSTANCES

MEMORANDUM

DATE: 17-FEB-1999

SUBJECT: PP# 9F3705. **Clofentezine on Apples**. Calculation of Anticipated Residues. Barcode D252865. Chemical 125501. Case 280778. Submission S552722.

TO/FROM: Jennifer E. Rowell, Chemist
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AgrEvo requests a label amendment for Apollo® SC on apples to allow late season applications (minimum 45 days PHI). Apollo is currently registered for early season use on apples up to the "tight cluster" stage. The petitioner proposes the establishment of tolerances for the residues of clofentezine in or on the following commodities:

Commodity	ppm	Commodity	ppm
Apples	0.5	Apple Pomace	3

In HED's preliminary assessment of this registration, the cancer risk for the U.S. population was found to exceed 1×10^{-6}. In order to further refine the cancer risk, the DEEM analysis was partially refined, incorporating % crop treated data and/or anticipated residues (ARs) for all commodities as appropriate. Table 1 lists the calculated ARs.

Table 1. Summary of Clofentezine Anticipated Residues for Dietary Risk Assessment[1]

Commodity	Residue to Use in Chronic DEEM Run (ppm)
Apples	0.12
Almonds	0.09
Nectarine	0.12
Peaches	0.13
Pears	0.15
Cherries	0.19
Apricots	0.44
Meat[2]	0.00004
Liver[2]	0.006
Kidney[2]	0.001
Meat by-products[2]	0.00004
Fat[2]	0.00004
Milk	0.0003

1. %CT data are not incorporated into ARs for RACs. The %CT data will be used in the DEEM analysis.
2. These anticipated residues should also be used for meat, fat and meat by-products of beef, horses, goats, sheep and veal in the DEEM run.

RACs

The average field trial value from the crop field trials was used for all crops. For those trials for which quantifiable residues were not found, a value of ½ LOQ was used.

Meat and Milk

Table 2. Anticipated Dietary Burden for Beef and Dairy Cattle

Feed Item	Average AR/%DM[1]	% in Diet[2]		Anticipated Dietary Burden[3]	
		Beef	Dairy	Beef	Dairy
Apple Pomace	0.425	40	20	0.17	0.084

[1] Average AR/%DM = average of anticipated residues in feed items divided by the % dry matter (%DM) for the feed item. AR: 0.17 ppm for apple pomace. %DM: 40% for apple pomace. **Note: The ARs incorporate % crop treated (24%).**

[2] The % of each feed type assumed to be included in the diet was based on information contained in the revised Table I of the OPPTS Test Guidelines Series 860.

[3] The anticipated dietary burden is calculated by multiplying the average AR/%DM by the % of the feed item in the diet.

Residue data on ruminant commodities have been previously reviewed by HED (Memo, H. Fonouni 12/15/88; DEB Nos. 4600-4601). HED has calculated the anticipated dietary burden

for beef and dairy cattle (0.17 ppm and 0.084 ppm, Table 2). There are two animal feed items associated with this petition, almond hulls and apple pomace. Only apple pomace will be used to calculate the anticipated dietary burden as both of these items are regional in nature and using apple pomace results in a higher dietary burden. The highest dosing levels used in the ruminant feeding study (100 ppm) correspond to 588X and 1190X the anticipated dietary burden for beef and dairy cattle, respectively. Based on this information, and based on the residues found in meat, meat by-products, fat and milk in this study (Table 3), the anticipated residues in livestock commodities to be used in the chronic dietary risk assessments are shown below:

meat	0.00004 ppm
liver	0.006 ppm
kidney	0.001 ppm
meat by-products (except liver and kidney	0.00004 ppm
fat	0.00004 ppm
milk	0.0003

Note: For liver, the ARs were calculated as the average of the three feeding levels (10, 30 and 100 ppm). For kidney and milk, the two highest feeding levels (30 and 100 ppm) were used to calculate the ARs as residues were <LOQ at the lowest feeding level. The ARs for muscle and fat were calculated using the highest feeding level (100 ppm) and a residue level of ½ LOQ since the residues were <LOQ in these matrices.

Table 3. Residues of clofentezine and its metabolites in milk and tissues of lactating cows dosed at 10 ppm, 30 ppm, and 100 ppm for 28 days.

Matrix	Dose Level (ppm)		
	10	30	100
	---------- Total Residue (ppm) [a] ----------		
Milk	<0.05	0.13	0.25
Liver	0.30	1.3	2.8
Fat	<0.05	<0.05	<0.05
Muscle	<0.05	<0.05	<0.05
Kidney	<0.05	0.23	0.50

[a] Total residue is the sum of clofentezine and its metabolites.

cc: Clofentezine List A File, S.F., J. Rowell (RAB1)
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